

Serial No. 10/806,795

Dkt.: P-9006.04

Filing Date: March 23, 2004

Title: HEMOSTATIC SYSTEM AND COMPONENTS FOR EXTRACORPOREAL CIRCUIT

**Amendments to the Claims:**

This list of the claims will replace all prior versions, and listings, of claims in the application.

**Listing of the Claims**

1. (Currently amended) A system for use in combination with an extracorporeal blood flow circuit, the system comprising: a) one or more automated sensor modules adapted to monitor, directly or indirectly, the presence of one or more blood ~~parameters~~ analytes, and b) one or more regulating modules adapted to affect the presence, concentration and/or activity of one or more blood ~~parameters~~ analytes, wherein the sensor module is adapted to incorporate flow injection analysis ("FIA") techniques, and comprises: i) a blood withdrawal component with in-line access, ii) an analytical component, and iii) a readout component.

2. (Currently amended) A system according to claim 1 wherein the monitored blood ~~parameters~~ analyte ~~[[,]]~~ and the regulated blood ~~parameters~~ analyte ~~are~~ is a protease inhibitor, the inhibitor's substrate, a precursor thereof, a derivative thereof, or a combination thereof.

3-6. (Canceled)

7. (Currently amended) A system according to claim 6 1, wherein the sensor module provides semicontinuous and/or continuous sampling of the blood analyte, in order to provide substantially real-time digital output readings of the monitored ~~parameter~~ analyte.

8. (Original) A system according to claim 1 wherein the regulating modules comprise a filter adapted to remove inflammation mediators from the blood, the filter providing a support surface selected from the group consisting of a specific binding ligand or hydrophobic surface.

Serial No. 10/806,795

Dkt.: P-9006.04

Filing Date: March 23, 2004

Title: HEMOSTATIC SYSTEM AND COMPONENTS FOR EXTRACORPOREAL CIRCUIT

9. (Original) A system according to claim 8 wherein the inflammation mediators are selected from the group consisting of anaphylatoxins, chemokines, and proinflammatory cytokines, and the support surface comprises a hydrophobic surface selected from the group consisting of acrylic polymers selected from the group consisting of acrylonitrile polymers, copolymers and polymer blends; polysulfones; polyamides selected from the group consisting of Nylon-6, Nylon-6,6, Nylon-11, Nylon-12, Nylon 6,9, Nylon-12; and acrylic and methacrylic ester polymers.

10. (Original) A system according to claim 1 comprising a regulating module adapted to remove heparin from the blood stream by anionic exchange of heparin with an immobilized positively charged species on the surface of a membrane.

11. (Currently amended) A method for monitoring and regulating blood ~~parameters~~ analytes in the course of extracorporeal blood flow, the method comprising: a) providing an extracorporeal blood flow circuit comprising, in the order of blood flow, a reservoir, a pump, and oxygenator, a filter, together with associated tubing, connectors and controls, b) providing a system comprising i) one or more automated sensor modules adapted to monitor, directly or indirectly, the presence of one or more blood ~~parameters~~ analytes, and ii) one or more regulating modules adapted to affect the presence, concentration and/or activity of one or more blood ~~parameters~~ analytes, c) employing the sensor module(s) to monitor one or more blood ~~parameters~~ analytes, and d) employing the filter module(s) to affect the presence, concentration and/or activity of one or more blood ~~components~~ analytes, wherein the sensor module is adapted to incorporate flow injection analysis ("FIA") techniques, and comprises: i) a blood withdrawal component with in-line access, ii) an analytical component, and iii) a readout component.

12. (Currently amended) A method according to claim 11 wherein the monitored blood ~~parameters~~ analytes[[,]] and the regulated blood ~~parameters~~ analytes ~~are~~ is a protease inhibitor, the inhibitor's substrate, a precursor thereof, a derivative thereof, or a combination thereof.

Serial No. 10/806,795

Dkt.: P-9006.04

Filing Date: March 23, 2004

Title: HEMOSTATIC SYSTEM AND COMPONENTS FOR EXTRACORPOREAL CIRCUIT

13-16. (Canceled)

17. (Currently amended) A method according to claim ~~16~~ 11 wherein the sensor module provides semicontinuous and/or continuous sampling of the blood, in order to provide substantially real-time digital output readings of the monitored parameter.

18. (Original) A method according to claim 11 wherein the regulating modules comprise a filter adapted to remove inflammation mediators from the blood, the filter providing a support surface selected from the group consisting of a specific binding ligand or hydrophobic surface.

19. (Original) A method according to claim 18 wherein the inflammation mediators are selected from the group consisting of anaphylatoxins, chemokines, and proinflammatory cytokines, and the support surface comprises a hydrophobic surface selected from the group consisting of acrylic polymers selected from the group consisting of acrylonitrile polymers, copolymers and polymer blends; polysulfones; polyamides selected from the group consisting of Nylon-6, Nylon-6,6, Nylon-11, Nylon-12, Nylon 6,9, Nylon-12; and acrylic and methacrylic ester polymers.

20. (Currently amended) A method according to claim ~~1~~ 11 comprising a regulating module adapted to remove heparin from the blood stream by anionic exchange of heparin with an immobilized positively charged species on the surface of a membrane.

21. (New) The system of claim 2 wherein the protease inhibitor is aprotinin.

22. (New) The system of claim 2, wherein the substrate is kallikrein.

23. (New) The system of claim 2, wherein the precursor is prekallikrein, FKIIa, FKII or a combination thereof.

Serial No. 10/806,795

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Filing Date: March 23, 2004

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24. (New) The system of claim 1, further comprising one or more automated sensor modules adapted to monitor, directly or indirectly, one or more blood functions, and b) one or more regulating modules adapted to affect the activity of the one or more blood function.

25. (New) The system of claim 25, wherein the blood function is clotting time, fibrinolytic activity, or immune response.

26. (New) The method of claim 12 wherein the protease inhibitor is aprotinin.

27. (New) The method of claim 12, wherein the substrate is kallikrein.

28. (New) The method of claim 12, wherein the precursor is prekallikrein, FKIIa, FKII or a combination thereof.

29. (New) The method of claim 12, wherein the system further comprises one or more automated sensor modules adapted to monitor, directly or indirectly, one or more blood functions, and b) one or more regulating modules adapted to affect the activity of the one or more blood function.

30. (New) The method of claim 29, wherein the blood function is clotting time, fibrinolytic activity, or immune response.